IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This Document Relates To: *All Actions*	Hon. Robert. B. Kugler Civ. No. 19-2875 (RBK/JS)

THIRD-PARTY PAYORS' OPPOSITION TO DEFENDANTS' JOINT MOTION TO EXCLUDE THE OPINIONS OF KALIOPI PANAGOS, PHARM.D., R.Ph.

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Defendants challenge expert testimony by Dr. Kaliopi Panagos on numerous grounds. Their criticism of Dr. Panagos is unfounded. She is qualified as an expert by knowledge, skill, experience, training, and education, and her testimony will help the trier of fact to understand the evidence and determine a fact in issue. Defendants' motion should be denied.

LEGAL STANDARD

"Under the Federal Rules of Evidence:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998) (quoting Fed. R. Evid. 702). "For a court to qualify a witness to testify as an expert, Rule 702 requires the witness to have 'specialized knowledge' regarding the area of testimony"—and "[t]he basis of this specialized knowledge 'can be practical experience as well as academic training and credentials.'" *Id*. (quoting *American Tech. Resources v. United States*, 893 F.2d 651, 656 (3d Cir.1990)); *see also Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 590 (1993) ("Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known."). The Third Circuit has "interpreted the specialized knowledge requirement liberally, and [has] stated that this policy of liberal admissibility of expert testimony 'extends to the substantive as well as the formal qualification of experts.'" *Waldorf*, 142 F.3d at 625 (quoting *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 741 (3d Cir. 1994)). The baseline requirement is simply that "a proffered expert witness . . . must possess skill or knowledge greater than the average layman . . . ." *Id*. (quotation marks omitted). "If the expert meets liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997), *as amended* (Dec. 12, 1997).

ARGUMENT

I. DR. PANAGOS IS QUALIFIED TO TESTIFY AND HAS IDENTIFIED THE SUPPORT FOR HER TESTIMONY

Citing to *Daubert v. Merrell Dow Pharms., Inc.*, Defendants ask the Court to exclude Dr. Panagos's opinions on the theory that they are "not based on any methodology, as reflected by her utter failure to identify the bases supporting her various opinions." (Mot. at 8.) According to the Defendants, Dr. Panagos did not show that she followed a "scientific method," and she "presented no quantifiable data" to support her opinion. (Mot. at 8-9.) They claim (no less than eight times) that her opinion is nothing more than "*ipse dixit*." (Mot. at 3, 8, 18, 24, 27, 29, 30.) Defendants also accuse Dr. Panagos of not "providing footnotes or textual citations identifying specific references for the individual numbered paragraphs in her Report," and of insisting in her deposition "that every individual opinion was based on *every single item* in the appendix to her Report." *Id.* at 9. In so doing Defendants misunderstand and mischaracterize Dr. Panagos's testimony and her report, and misconstrue applicable law.

Contrary to what Defendants claim, the *Daubert* reliability factors do not apply to the type of specialized knowledge that supports Dr. Panagos's testimony. As set out in Rule 702, an expert may testify based on "scientific, technical, or other specialized knowledge. . . ." Fed. R. Evid. 702(a). The Sixth Circuit explained the difference between these areas of expertise using the example of a bumblebee:

> The distinction between scientific and non-scientific expert testimony is a critical one. By way of illustration, if one wanted to explain to a jury how a bumblebee is able to fly, an aeronautical engineer might be a helpful witness. Since flight principles have some universality, the expert could apply general principles to the case of the bumblebee. Conceivably, even if he had never seen a bumblebee, he still would be qualified to testify, as long as he was familiar with its component parts.
>
> On the other hand, if one wanted to prove that bumblebees always take off into the wind, a beekeeper with no scientific training at all would be an acceptable

> expert witness if a proper foundation were laid for his conclusions. The foundation would not relate to his formal training, but to his firsthand observations. In other words, the beekeeper does not know any more about flight principles than the jurors, but he has seen a lot more bumblebees than they have.

Berry v. City of Detroit, 25 F.3d 1342, 1349–50 (6th Cir. 1994).

Dr. Panagos's opinion here is like that of the beekeeper; her testimony is based more on her professional expertise than on the application of general scientific principles. She has specialized knowledge as to what TPPs and PBMs rely on because she has been a practicing pharmacist for 15 years, taught pharmacy classes for 5 years, dealt extensively with P&T committees, and has a doctorate in pharmacy. (Panagos Report, D.E. 2034-3.)

Because Dr. Panagos's expertise is based on "practical experience, rather than academic theories," the *Daubert* reliability inquiry focuses on her "knowledge and experience . . ., rather than the methodology or theory behind it." *States v. Fernwood Hotel & Resort*, 2014 WL 198568, at *3 (M.D. Pa. 2014) (citing *U.S. v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000)); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he relevant reliability concerns may focus upon personal knowledge or experience."); *Fernwood Hotel*, 2014 WL 198568, at *4 (examining a proposed expert's qualifications "because [the expert's] opinion is based solely on his experience," and finding that "[h]is years of experience and relevant expertise provide the necessary support for his opinions.").

Courts in this Circuit have repeatedly found expert opinions to be reliable when they are based on the type of specialized experience Defendants dismiss as "*ipse dixit*." In *U.S. v. Vaghari*, the court found that an expert's opinion as to the "*[m]odus operandi* among those attempting to evade the Iran embargo" was reliable based on his "significant academic and practical experience regarding Iran sanctions." 735 F. Supp. 2d 197, 204 (E.D. Pa. 2010). In

Fernwood Hotel, the court found that an expert's opinion that a "glass structure was at least twenty-five years old and had not been properly maintained" was reliable based on his experience "installing glass and serving as a glass consultant on major projects." 2014 WL 198568, at *1-3. And in *U.S. v. Schiff*, the court found an expert qualified to testify "on what information is important to a reasonable investor" based on his "experience in investing client assets and valuing companies, including pharmaceutical companies." 538 F. Supp. 2d 818, 845 (D.N.J. 2008), *aff'd*, 602 F.3d 152 (3d Cir. 2010).

Here, Dr. Panagos's opinions are reliable based on her over 20 years of experience in the pharmaceutical industry. Dr. Panagos is the Executive Vice President of ARMSRx Pharmacy Benefit Consulting, an organization that provides pharmacy benefits guidance to self-insured employers, brokers, and TPAs/TPPs. (D.E. 2034-3.) She has served on the faculty and administration of Long Island University's College of Pharmacy, and she has dedicated over ten years to the managed care and pharmacy consulting industry, overseeing clinical development, overall PBM operations, and client services/management, working primarily with TPAs and TPPs. *Id.* She also was the subject matter expert on all PBM, clinical, drug, and specialty items at Broadreach Medical Resources, Inc. for over ten years. *Id.* She was the director of clinical services at SmithRx, a start-up pharmacy benefit administrator. *Id.* And she has a bachelor's degree and a doctorate in pharmacy. *Id.* As such, she undoubtedly has "skill or knowledge greater than the average layman" on the subject matter of her testimony, and is therefore qualified to testify as an expert. *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (citing *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir.1987)).

Defendants criticize Dr. Panagos for not "provid[ing] footnotes or textual citations identifying specific references for the individual numbered paragraphs in her Report." (Mot. at

9). But that is not required by Rule 26,[1] and in any event, Dr. Panagos's report does contain footnotes that provide specific support. *See* D.E. 2034-3 at 1, 4, 5, 6, and 8. Defendants also claim that during her deposition Dr. Panagos "kept insisting that every individual opinion was based on *every single item* in the appendix to her Report." *Id.* at 9. But that is not what happened. Defendants cite to four lines of Dr. Panagos's deposition, where she testified as follows:

> Q. And what did you rely on in formulating the statements that you've included on Paragraphs 19 and 20 of your report?
>
> A. My professional experience, my pharmacy knowledge and education, and the materials in Appendix A.

(Panagos Dep. 99:17-21.) Immediately afterward, however, defense counsel asked for more specificity, and Dr. Panagos provided it:

> Q. And with respect to the materials in Appendix A, which of the materials listed in Appendix A formed the basis for your statements in Paragraphs 19 and 20 of your report?
>
> A. The American Journal of Managed Care, ASHP, Coordination of Benefits, Formulary Development, The Journal of Managed Care, Drug -- Navigating Drug Formularies and Pharmacy Benefit Management, the Orange Book, Principles of a Sound Drug Formulary, and the U.S. Food and Drug Administration Development Approval Process.

(Panagos Dep. 99:22-100:6.) Defendants' characterization of Dr. Panagos's testimony is simply incorrect.[2]

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[1] Rule 26 requires that the expert report state "the basis and reasons" for the opinions; there is no requirement that they appear in a footnote, as opposed to in the text of the report, the expert's resume, or the appendix of materials which the expert considered. Dr. Panagos's resume and the appendix of materials on which she relied are exhibits that can be found at D.E. 2034-3.

[2] Defendants point to seven additional lines of testimony (Panagos Dep. 99:6-14) to support their argument. (Mot. at 9.) But that testimony follows a page of testimony where Dr. Panagos identified the specific support for paragraphs 14 through 18 of her report by citing to specific entries in her appendix of materials she considered. (Panagos Dep. 97:7-99:5.) When defense counsel pressed her to identify additional support, Dr. Panagos stated that the appendix covered the entirety of her report, so she would have to review the appendix to make sure that she didn't miss any support for those specific paragraphs. That is a far cry from Defendants' (false) claim

II. DR. PANAGOS'S OPINIONS ON BIOEQUIVALENCE, FDA APPROVAL, AND ADDITION OF A DRUG TO THE ORANGE BOOK SHOULD NOT BE EXCLUDED

Defendants try to dismiss Dr. Panagos's opinions as "speculative" and lacking in "intellectual rigor" (Motion at 12 (alteration in original)). Contrary to their portrayal of Dr. Panagos as some sort of neophyte, she has "over 20 years of experience, half of which has been dedicated to the managed care and pharmacy consulting industry overseeing Clinical Development, overall PBM Operations & Client Services/Management," working primarily with TPPs. (D.E. 2034-3 at ¶ 7.) Her opinions are based on her expertise and specialized knowledge. *See Fernwood Hotel*, 2014 WL 198568, at *3 ("[C]ourts have held that when examining expert testimony that is based on practical experience, rather than academic theories, the *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable, because the reliability of testimony from a practical experience expert depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.") (citations and quotations omitted). She is well qualified to testify based on her professional experience and expert-level understanding of the concept bioequivalence, the FDA approval process, and the Orange Book.

A. Dr. Panagos's Regulatory Opinions on Bioequivalence, FDA Approval, and Inclusion in the Orange Book Are Supported and Reliable

1. *Dr. Panagos's Bioequivalence Opinions Are Reliable*

Dr. Panagos declares in ¶ 51 of her expert report that "[i]n order to obtain FDA approval of a generic drug as an Orange Book listed drug, a manufacturer is required to demonstrate that its generic drug is bioequivalent to the RLD." She goes on to say that when TPPs "agree to

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that Dr. Panagos testified that "every individual opinion was based on *every single item* in the appendix to her Report." (Mot. at 9.)

reimburse for generic drugs such as valsartan including VCDs, they do so based on the warranties made by manufacturers that their drug product is in compliance with the FDA, bioequivalent of the Orange Book reference drug and safe to be sold to consumers." (D.E. 2034-3 at ¶ 56.) Defendants argue that Dr. Panagos "does not even know the FDA definition of bioequivalence—much less connect it to her opinion." (Mot. at 14.) But that is just not the case. Dr. Panagos testified quite clearly that she understands what "bioequivalence" means in her profession. *See* Panagos Dep. at 172:12-16 ("It's part of the scope of my profession . . . . It's within the scope of my profession as a pharmacist that bioequivalent is within that knowledge base.").[3]

Defendants assert, without elaboration, that "none of [Dr. Panagos's] definitions of "bioequivalent drug products," "bioequivalent," or "bioequivalence" match the definition of "bioequivalence" in the Code of Federal Regulations (21 C.F.R. § 314.3)." (Mot. at 14 (citations omitted).) But Dr. Panagos rejected this characterization of her report. *See* Panagos Dep. at 177:18 ("A. No, I don't agree" that the language in the report "is not the definition of bioequivalence from the Code of Federal Regulations.") She further testified that "Page 6, Section E under 33 [of her report] has the definition for bioequivalent drug products." (Panagos Dep. at 171:25–172:1.) Defendants misleadingly quote Dr. Panagos saying "I did not review" (Mot. at 14), without acknowledging the ensuing exchange:

> Q. My question is, Doctor, . . . in the process of preparing your report, did you review the definition of bioequivalent contained within the Code of Federal Regulations?
>
> A. Yes…
>
> A. I believe my definition in my report captures what a bioequivalent drug product – captures the definition appropriately."

[3] *See also* Panagos Dep. at 54:14-19, 136:12-22.

(Panagos Dep. at 177: 5-9; 178:3-5.) Dr. Panagos was clear—she did in fact review the definition of bioequivalent contained within the Code of Federal Regulations in the process of preparing her report. *Id.* And even if she did not, there is of course no requirement that experts reread specific regulations before forming their opinions. Defendants' characterization of her understanding of the term as "subjective" (Mot. at 14) is inconsistent with her actual testimony that her understanding is based on the "definition of bioequivalent contained within the Code of Federal Regulations." (Panagos Dep. at 177:5-9.)

Defendants next argue that Dr. Panagos "lack[s] a methodology for opining that Defendants' VCDs failed to meet her subjective definition" of bioequivalence, that she failed to "to identify any documents that would support the absence of bioequivalence in Defendants' VCDs," and that she failed to "conduct her own research or analysis of bioequivalence." (Mot. at 15.) But Dr. Panagos was not required to use a scientific "methodology" to "conduct her own research or analysis of bioequivalence" in order to form a reliable and admissible expert opinion. "[W]hen examining expert testimony that is based on practical experience, rather than academic theories . . . the reliability of testimony from a practical experience expert 'depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.'" *Christoforetti v. Bally's Park Place, Inc.*, 2021 WL 3879074, at *6 (D.N.J. 2021) (quoting *States v. Fernwood Hotel & Resort*, 2014 WL 198568, at *3 (M.D. Pa. 2014)). Experts are permitted to testify based on their education and experience; they are not required to conduct original scientific research.

Defendants argue that Dr. Panagos's "failure to review any literature, studies, or data" regarding the presence of NDMA or NDEA "renders her bioequivalence opinions fatally unreliable." (Mot. at 16.) But the case Defendants cite does not stand for the proposition that an

expert is necessarily required to "review . . . literature, studies, or data" in forming her opinion. The problem in *Ruggiero v. Yamaha Motor Corp.*, 2017 WL 1197755 (D.N.J. 2017) was that an expert who offered the opinion that a personal watercraft with warning labels in two locations should also have had one in a third location had not taken any measurements or done any testing or reconstruction "to support his presumption that a passenger boarding from the side of the craft would not see" the two existing labels, and "[w]ith no measurements or reconstruction, it is guesswork whether a passenger would be apt to notice the front label while riding." *Id*. at *7. Here, Dr. Panagos is not proposing a new theory or technique that needed to be tested; she is simply explaining and applying basic concepts in her field. *Ruggiero* does not stand for the proposition that an expert is required to employ any particular methodological tool in every case.

Also failing to advance Defendants' cause is *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781 (3d Cir. 2009), as the key problem there was that the plaintiff's accident-reconstruction expert had failed to replicate the conditions at the time of the accident when conducting his testing on a defective valve. *Id*. at 789. Here, however, Dr. Panagos is not trying to figure something out or solve a novel problem; she is simply stating what should be the uncontroversial scientific fact that the drugs at issue in this case are not bioequivalent. This is a different kind of expert testimony than that of an accident-reconstruction expert who needs to perform testing to figure out what happened. Dr. Panagos did not need to conduct any experiments to ascertain, based on her professional experience and education, that the presence of the NDMA or NDEA contaminants rendered the manufacturer Defendant's versions of VCDs not equivalent to the branded product based on the fact that "[t]he contaminants were not in the branded product and therefore the generic drug could not have been equivalent to the branded product by the presence of the contaminants within the product." (Panagos Dep. at 141:24–

142:6.) Nor do her bioequivalence opinions need to be based on a contemporaneous review of "literature, studies, or data" on the presence of NDMA or NDEA in order for her to be qualified as an expert. Instead, her opinion is based on her understanding that generic drugs must be bioequivalent to the branded drug, meaning the generic drug will work the same way in the body and be as safe and effective as the brand name drug. *See* D.E. 2034-3 at ¶ 44; Panagos Dep. at 114:20-24. That is something Dr. Panagos knows based on "[her] education, [her] degrees, [her] licensure as a pharmacist," "[her] experience and the items [she] listed in the appendix," all of which is "a critical component to performing [her] day-to-day functions and understanding that foundational component." (Panagos Dep. at 114:25–115:8.) Her bioequivalence opinions are reliable.

2. *Dr. Panagos's FDA Approval and Orange Book Opinions Are Reliable*

Dr. Panagos's FDA-approval and Orange Book-inclusion opinions are also well supported. Dr. Panagos "understand[s] what the [approval of pharmaceutical products] process entails by the FDA." (Panagos Dep. at 66:3-6.) She has testified that "[t]he process for drug approval varies between brand and generics and [she] [has] an understanding of the process for . . . both of those drugs to be approved." (Panagos Dep. at 67:5-7.) Defendants contend that Dr. Panagos fails to "identify a regulation supporting her statement that manufacturers must 'understand[] their processes which includes preventing the presence of unacceptable . . . impurities,'" insisting that this is based "simply her own subjective belief" (Mot. at 16-17)—but they fail to explain why regulatory citations should be required to support the commonsense understanding Dr. Panagos has, based on her professional experience and education, that manufacturers must indeed understand their own processes. *See* Panagos Dep. at 130:9–131:6 ("Manufacturers are the ones submitting their application requesting approval; therefore, they are

responsible for all the information they provide within that application . . . . They are applying for approval, so they must adhere to the requirements set forth by the FDA in order to obtain that approval."). When asked what she was relying on in ¶ 52 of her report Dr. Panagos replied, "I'm relying on the fact that manufacturers submit applications for drug approval. *It's a common, known fact*." (Panagos Dep. at 131:7-12 (emphasis added).) *See Rsch. Corp. Techs., Inc. v. Microsoft Corp.*, 2009 WL 10673979, at *2 (D. Ariz. 2009) (experts may draw "inferences" from "known facts" if they are "based on good grounds.").

Dr. Panagos went on to testify that "[t]he FDA regulates that if a manufacturer is seeking approval of their drug, . . . if it's a generic drug . . . they must file an ANDA application and meet the requirements for approval." (Panagos Dep. at 131:16-23.) She added that it was "the industry accepted understanding" that "if a manufacturer is seeking approval of their drug, they must file an application with the FDA" and that "must meet the requirements set forth by the FDA to be compliant, safe, and effective." (Panagos Dep. at 131:24–132:8.) Dr. Panagos knows these things based on her professional experience and education and may testify about them as an expert on that basis.

Dr. Panagos testified that her opinion that P&T committees' and TPPs' reliance on the Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations, and as such are suitable for formulary placement and reimbursable under a prescription drug benefit plan, is based on her "education, experience, and familiarity with P&T committees," and "[her] day-to-day functions . . . keeping knowledgeable with the industry practice, functions, drug information." (Panagos Dep. at 132:9-18, 133:18-23.) She added, "[t]hat's all part of what I do so I'm comfortable with what's required or what components are essential." (Panagos Dep. at 133:24-25.) Her FDA-approval and Orange Book opinions are reliable and admissible.

B. Dr. Panagos Has the Necessary Expertise on Bioequivalence, FDA Approval, and the Orange Book

Defendants argue that Dr. Panagos has "no qualifications related to bioequivalence and therefore is wholly unqualified to opine as to the definition of bioequivalence and whether Defendants' VCDs met that definition at the time they were sold to Plaintiffs." (Mot. at 18.) Defendants go on to criticize Dr. Panagos for her lack of "published . . . articles relating to the FDA regulatory requirements," complaining that she has not "worked or consulted with FDA" or "done consulting work for any pharmaceutical company," or had "personal experience with the manufacturing of pharmaceutical products." *Id.* Defendants make similar arguments as to her "opinions regarding FDA approval or the purported implications of a drug's inclusion in the Orange Book." (Mot. at 18-19.) Defendants base these arguments on a checklist of qualifications and experiences that they insist are required for a person to be qualified as an expert on these topics. The Court should decline the invitation to impose requirements that are supported by neither caselaw nor common sense.

Dr. Panagos is a pharmacist by trade, not a career academic or government employee. She has worked in the private sector, most recently in a consulting role at ARMSRx Pharmacy Benefit Consulting, a nationally recognized, independent organization dedicated to providing pharmacy benefit guidance to self-insured employers, brokers and TPAs/TPPs. (D.E. 2034-3 at ¶ 7.) She explained that her "education and [her] experience are – involve those—aspects of bioequivalence, and those are part of the components" of her expertise. (Panagos Dep. at 54:17-20.) Dr. Panagos's "professional capacity includes advising [her] clients and providing them guidance on . . . various drug products, structure of their prescription benefit program, and approvals and drugs in good standing for consideration on the formulary." (Panagos Dep. at 57:9-13.) She also has "given presentations on drug products that are approved for use by the

FDA." (Panagos Dep. at 60:1-2.) Dr. Panagos's practical, real-world knowledge and extensive experience, in particular her knowledge and experience in the field of providing pharmacy benefit guidance to TPPs—exactly the issue she offers opinions about—qualifies her to give expert testimony in this case.

Defendants assert that "Dr. Panagos testified that she will not 'offer any opinions on the process for obtaining approvals from FDA for generic pharmaceutical products.'" (Mot. at 19.) But that is not what Dr. Panagos said; her answer to the question from which Defendants quote ("So you're not intending to offer any opinions on the process for obtaining approvals from FDA for generic pharmaceutical products") was this: "The process for approval of generic drug products is already established by the FDA." (Panagos Dep. at 75:11–17.) Defendants suggest that Dr. Panagos was being "evasive" when she responded to a question about whether she holds herself out as an expert on the process for approval of pharmaceutical products by the FDA by saying that she "understand[s] what the process entails by the FDA." (Mot. at 19; Panagos Dep. at 66:3–6.) She was clear, however, that "[t]he process for drug approval varies between brand and generics and I have an understanding of the process . . . for both of those drugs to be approved." (Panagos Dep. at 67:5–7.) *See also* Panagos Dep. at 67:14-22 ("I have been asked here today to render an opinion on what TPPs rely on when TPPs rely on or – or consult when they're making – with respect – specifically to generic drugs for formulary decisions, and specific to generic drugs, that process involves an approval by the FDA tied to an ANDA application whereby the manufacturer has to meet the criteria for approval in order for that generic drug to gain their approval. That's what I've been asked to render an opinion on."). After a contentious off-the-record exchange between counsel, Defendants yet again asked Dr. Panagos whether she was offering any opinions on the process of obtaining approvals from FDA for

generic pharmaceutical products. And if Dr. Panagos was not clear enough the first time, she repeated that "[she] [was] rendering an opinion on what TPPs, third-party payers, rely on with respect to generic drugs for consideration to a drug formulary," and that "[t]he process for approval of generic drug products is already established by the FDA." (Panagos Dep. at 75:3-17.) This is expert testimony that Dr. Panagos is qualified to give.

Defendants further argue that Dr. Panagos "lacks the specialized knowledge and expertise to offer her purported opinions on FDA's decisions on therapeutic equivalence evaluations and ratings in the Orange Book." (Mot. at 20.)[4] But she does in fact possess the requisite knowledge and expertise to review and explain what has *already been published* by the FDA in the Orange Book. Nothing more is required, beyond Dr. Panagos's existing knowledge and expertise, for her to perform this interpretative task. Dr. Panagos does not have to reinvent the wheel to analyze and opine on the Orange Book's therapeutic equivalence evaluations and ratings; she reviewed and can explain to a lay jury what the FDA has already done. *See* Panagos Dep. at 109:7-24.

Dr. Panagos's report and testimony are in line with what other courts have permitted. For example, courts have permitted experts to "offer testimony on what certain technical regulatory documents mean and how they exemplify compliance with industry standards/customs." *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prod. Liab. Litig.*, 2016 WL 4039271, at *9 (E.D. Pa. 2016). Courts have also allowed expert testimony on "[t]he FDA drug approval process, FDA regulations, and protocols of drug labeling." *Johnson v. Wyeth LLC*, 2012 WL

[4] Defendants cite (Mot. at 20) to *Abbott Labs. v. Mylan Pharms., Inc.*, 15 So. 3d 642, 656 (Fla. Ct. App. 2009), a state court case that was not about expert testimony, for the self-evident proposition that the Orange Book involves "complex science which the FDA uses to develop the list of generic drugs included in the Orange Book." *Id.* at 656. Of course formulations and descriptions of pharmaceutical drugs involve "complex science." But Dr. Panagos is a registered pharmacist with over 20 years of clinical, academic, and private sector pharmacy experience who is intimately familiar with the contents and processes of the Orange Book.

1204081, at *3 (D. Ariz. 2012); *see e.g., In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 478–79 (S.D.N.Y. 2016) (numerous courts have found that "the testimony of regulatory experts on the reasonableness of a pharmaceutical company's conduct in light of the complex nature of the FDA framework is helpful to a jury."); *Wells v. Allergan, Inc.*, 2013 WL 7208221, at *1 (W.D. Okla. 2013) (finding expert testimony about FDA regulations would not "usurp" the role of the trial judge); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (denying motion to preclude expert from "testifying about general FDA regulatory requirements and procedures or offering an opinion as to [the pharmaceutical company's] compliance therewith"). In particular, courts have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements under the FDA. *See, e.g., Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 659–60 (E.D. Pa. 2012) (experts permitted to testify that defendants withheld information from FDA and failed to conduct a proper safety analysis); *Bartoli v. Novartis Pharm. Corp.*, 2014 WL 1515870, at *7 (M.D. Pa. 2014) (finding that expert could opine on the reasonableness of defendant's conduct in its interactions with the FDA and compliance with FDA regulations, including defendant's interactions with FDA with respect to labels and warnings); *Pfizer v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 278–79 (D.N.J 2006) (allowing expert testimony on FDA regulation of labeling, advertising, and promotion of prescription drugs, and pharmaceutical company compliance with those requirements). Dr. Panagos possesses the relevant expertise, and her opinions should not be excluded.

C. Dr. Panagos's Opinions About Bioequivalence, FDA Approval, and the Orange Book Are Not "Impermissible Regulatory Conclusions"

According to Defendants, "Plaintiffs seek to offer Dr. Panagos's testimony as to Defendants' regulatory compliance as it relates to bioequivalence." (Mot. at 22.) But Dr. Panagos is not offering an opinion as to whether Defendants complied with a regulation; her

opinion is that "[i]f the generic manufacturer product changes in any way from the original product on the ANDA approval, then this changed product *is not the same* as the brand name medication . . . ." (D.E. 2034-3, Opn. D (italics added).) "The Third Circuit has permitted experts to opine on established industry customs and standards, provided the testimony stops short of defining the legal duties arising from industry customs or opining on whether the defendant has complied with those duties." *Mastripolito v. Jefferson Health-New Jersey*, 2022 WL 334169, at *2 (D.N.J. 2022) (quotation marks omitted) (citing *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 218 (3d Cir. 2006)). Dr. Panagos will not be testifying about whether Defendants have complied with their legal duties, but on established industry customs and standards for bioequivalence. That is a proper subject for expert testimony. *See id*.

In *Berckeley*, relied on by Defendants, the Third Circuit held that an expert in a securities case could not "testify as to whether Berckeley complied with legal duties that arose under the federal securities laws." 455 F.3d at 218. Dr. Panagos's testimony that contaminated VCDs are not the same as the brand name medication is not an opinion as to whether Defendants complied with legal duties that arose under federal law; it is information about what "equivalence" is understood to mean in the pharmaceutical industry that will aid the jury in determining whether Defendants are liable to Plaintiffs for breach of warranty, fraud, violation of consumer protection statutes, negligence, negligent misrepresentation, or unjust enrichment. Her testimony that contaminated VCDs are not the same as the brand name medication is not a legal opinion on the merits of any of Plaintiffs' claims, and is therefore permissible under *Berkeley*. *See id.* at 218 ("Key to our determination [that expert testimony was admissible in *United States v. Leo*, 941 F.2d 181 (3d Cir.1991)] was that the expert did not give his opinion as to what was required under the law, or whether the defendant complied with the [Armed Services Procurement] Act.

Rather, the testimony was permissible because the expert testified, based upon his experience in the defense industry, as to how firms such as [the defendant's] operated when performing contracts governed by the Act.") (quotation marks omitted).

"An opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704(a). That does not mean an expert may "merely tell the jury what result to reach." *Krys v. Aaron*, 112 F. Supp. 3d 181, 192 (D.N.J. 2015) (quotation marks omitted). But while "an expert may not render any ultimate opinion concerning, for example, whether a specific party had capacity to make a will," they "may offer an opinion concerning whether that party had sufficient mental capacity to know the nature and extent of his property and the natural objects of his bounty and to formulate a rational scheme of distribution." *Id*. at 192–93 (quotation marks omitted). "In other words, under Rule 704, an expert may not make a conclusory statement on a party's capacity, but may provide testimony that touches the underlying issues relevant to a determination of capacity." *Id*. at 193. An expert "may provide an opinion on whether a party's conduct or actions meet the underlying bases for an ultimate issue in a case," so long as they do not "merely instruct the jury on the result to reach based upon a party's specific conduct or actions (by, for example, stating that a party did indeed violate an applicable duty through certain actions)." *Id*.; *see also United States v. Xue*, 2022 WL 1027634, at *12–13 (E.D. Pa. 2022) (government's expert witnesses could not use legal term of art "trade secrets," but could testify "that the information at issue was confidential or proprietary information, that the information has economic value in the industry, and that steps are taken by GSK and other companies to preserve or keep confidential this information," and about "customs and practices in the biopharmaceutical industry," so long as the term "trade secrets" was not used).

Dr. Panagos's testimony on bioequivalence does not "instruct the jury on the result to reach" (*Krys*, 112 F.Supp.3d at 193) on any of Plaintiffs' claims. It does bear on whether Defendants' "conduct or actions meet the underlying bases for an ultimate issue in a case" (*id*.)—but that is permissible expert testimony. *Id*. at *8 (an expert "may testify to those facts that bear upon the ultimate issue but may not state any blunt legal conclusion as to whether National Beef violated any portion of the ADA."); *see Orner v. Nat'l Beef Packaging Co., LLC*, 2015 WL 8334544, at *7 (M.D. Pa. 2015) ("'[A]n expert may offer his opinion as to facts that, if found, would support a conclusion that the legal standard at issue was satisfied, but he may not testify as to whether the legal standard has been satisfied.'") (quoting *Burkhart v. Washington Metro. Area Transit Auth*., 112 F.3d 1207, 1212–13 (D.C. Cir. 1997)).

Also permissible is Dr. Panagos's testimony about "the requirements for, and significance of, FDA approval of a drug" and "FDA's regulatory process with respect to the Orange Book." (Mot. at 23.) This is "background testimony" that "could be helpful to the jury." *Berckeley*, 455 F.3d at 218. "[C]ourts have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements under the FDA." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*., 2020 WL 6887885, at *45 (E.D. Pa. 2020). While an expert cannot "opine that the defendants breached their legal duties," they may testify about "[t]he FDA drug approval process, FDA regulations, and protocols of drug labeling," because these are "topics that are likely unfamiliar to a layperson, and expert testimony on these topics will be helpful to the jury's understanding of the complex issues in this case." *In re: Tylenol*, 2016 WL 4039271, at *8–9 (E.D. Pa. 2016) (quotation marks omitted). It is precisely because bioequivalence and other concepts at issue in this case have "specialized legal meaning" (Mot. at 22) that expert testimony that explains the complex FDA regulatory scheme would be helpful to

the jury. Dr. Panagos will not be testifying about "whether Defendants complied with," or did not comply with, particular regulations.[5] (Mot. at 23.)

Dr. Panagos is not offering "legal or regulatory opinions," or "opinions on a pharmaceutical company's compliance with applicable regulations." (Mot. at 21). Instead, she is explaining why FDA approval matters and how the process works, and that the drugs at issue were not as Defendants had represented them to be. This is permissible expert testimony.

III. DR. PANAGOS'S "WARRANTY" OPINIONS ARE APPROPRIATE EXPERT TESTIMONY

A. Dr. Panagos Does Not Use the Word "Warranty" as a Legal Term of Art

Defendants are correct that Dr. Panagos "did not use the term 'warranty' in its legal sense" in her report. (Mot. at 24.) Dr. Panagos is not a lawyer, and she is not rendering a legal opinion; by "warranty" Dr. Panagos means Defendants' "promise or assurance that their drug is safe and effective and equivalent to the referenced listed drug product . . . ." (Panagos Dep. 122:22–24); *see also id.* at 123:2–7 ("Q. When you use the term warranty in your report, do you understand that to be a legal term? . . . A. No. It's a term that refers to a promise, an assurance, a guarantee that that manufacturer has set forth."). As an expert on pharmaceuticals, she may testify to the fact that Defendants made representations about their drugs that were false; she is not testifying about the legal consequences of this conduct.

Dr. Panagos's opinions are more than just "her own subject musings and *ipse dixit*." *Id.* Her opinion that Defendants represented to the FDA that the VCDs at issue here were the same

[5] Nor will Dr. Panagos be doing what the court found impermissible in *In re Rezulin Prod. Liab. Litig.* (cited by Defendants), which was to opine that "physicians would not have prescribed Rezulin if [defendant] Warner–Lambert had provided different information" to them—an opinion the court found to be "purely speculative and not based on scientific knowledge." 309 F. Supp. 2d 531, 556–57 (S.D.N.Y. 2004) (quotation marks omitted).

as the brand name drug, and that the FDA relied on this representation,[6] is based on her experience as a registered pharmacist, consultant on pharmacy benefits, and college of pharmacy faculty member (D.E. 2034-3 ¶¶ 5–9). She should be permitted to testify that the representations Defendants made to the FDA about their VCDs were, due to the contamination, factually incorrect. Defendants are of course free to challenge that opinion on cross-examination, but there is no basis for excluding it.

Defendants further object to Dr. Panagos's opinion that the representations they made to the FDA were false on the ground that it "depends on her own *personal* understanding of the word contaminants . . . ." (Mot. at 24 (emphasis in original).) But as just explained, what Defendants dismissively characterize as Dr. Panagos's *personal* understanding is (by Defendants' own account (*see* Mot. at 25 n. 14)) the product of "[her] industry knowledge, [her] pharmacy background, [her] education, studies, and professional scope in [her] career." (Panagos Dep. 95:16–17.) That is a proper basis for expert testimony, as "[i]t is well settled that an expert may base [her] opinions on [her] experience in [her] specialized field." *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 2013 WL 12164773, at *6 (D.N.J. 2013); *see also In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994) ("We have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications."); *Travelers Prop. Cas. Co. of Am. v. Hallam Eng'g & Constr. Corp.*, 2012 WL 13029519, at *6 (D.N.J. 2012) (permitting expert to testify "relying upon his 10 years of experience as a forensic accountant"); *United States ex rel. Penelow v. Janssen Prod., LP*, 2022 WL 94535, at *10

[6] Plaintiffs note that while *their* reliance on Defendants' misrepresentations is an element of their fraud claim, *the FDA's* reliance on Defendants' misrepresentations—although relevant to Plaintiff's claims—is not an element of Plaintiffs' claims.

(D.N.J. 2022) (Witness's "career in pharmacy administration gives him the specialized knowledge required to qualify as an expert under Rule 702.").

Defendants next complain that Dr. Panagos "relies on the statements made by the FDA . . . that some VCDs may have exceeded 'acceptable' levels of nitrosamines" rather than conducting and reporting on her own investigation (Mot. at 25); that she did not include the "time frame during which the purported 'warranties' were 'false'" in her report (*id.*); and that she did not know the precise "levels of NDMA or NDEA that were found in any particular lot of [VCDs]." *Id.* at 26 (quotation marks omitted). Again, Defendants are free to cross-examine Dr. Panagos about the scope of her opinions, but they cite no authority to support their apparent position that the opinions she does offer should be excluded because she does not also offer additional opinions or recite additional facts that Defendants believe she should have offered or recited.

Defendants cite *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 2021 WL 6051382, at *4 (E.D. Pa. 2021) as a case where an opinion was excluded "because the expert did not 'independently review the epidemiological research cited by . . . IARC'" (Mot. at 26)—but they neglect to mention that this was just one of an extended list of major problems the court had with this expert. *See, e.g.*, *id.* at *4 ("The sources Dr. Busse relies on do not support his opinion that smokeless tobacco, including Skoal and Red Man, can in general cause tonsil cancer."); *id.* at *5 ("In addition to relying on multiple sources that do not justify his view, Dr. Busse ignores other information and research. . . . He did not do an 'in depth' review of any epidemiological research published after 1981."); *id.* at *6 ("Dr. Busse's belief that it is biologically plausible for smokeless tobacco products like Red Man or Skoal to cause tonsil cancer does not account for the absence of data to support general causation."). Defendants also cite *Ruggiero* as having

excluded an opinion "where the expert 'failed to perform any tests' or 'rely on any [pertinent] articles'" (Mot. at 26)—but *Ruggiero* does not stand for the proposition that an expert is required to use any particular methodological tool. *See supra* at 10. — Nothing in these cases supports excluding Dr. Panagos's testimony.

B. Dr. Panagos Is Qualified to Testify About the Significance of the Orange Book

Defendants object to Dr. Panagos's opinion that "[t]he 'AB' rating in the FDA Orange Book, based as it is on the generic drug manufacturer's ANDA, represents a manufacturer's warranty to TPPs and P&T Committees for placement on a prescription drug formulary" (D.E. 2034-3 ¶ 47), on the grounds that she "lacks any specialized knowledge or expertise to render this opinion." (Mot. at 27.) That is so, Defendants claim, because Dr. Panagos "has never worked with or for the FDA or published anything on the topic of warranties, and knows no more about the composition of the Orange book than what can be gleaned from its preface . . . ." *Id*. These objections are unfounded.

As a registered pharmacist, consultant on pharmacy benefits, and college of pharmacy faculty member (D.E. 2034-3 ¶¶ 5–9), Dr. Panagos need not have "worked with or for the FDA" to understand and explain to lay jurors what a drug being listed in the Orange Book means. Nor is it a valid objection to her testimony that she has not "published anything on the topic of warranties," given that (as explained above) Dr. Panagos uses the term "warranty" simply to mean "representation," not as a technical legal term. As for the claim that Dr. Panagos "knows no more about the composition of the Orange book than what can be gleaned from its preface" (Mot. at 27), Defendants offer no record citation to support this baseless attack, and in any event, the point of her testimony is not that she is an expert on the Orange Book's "composition," but that she is an expert on *how it is used* and *what it means* in the industry. *See* Panagos Dep. at

153:8–14 ("The use of the Orange Book is an established process that is widely accepted and respected. It is the source of truth in terms of approved products, approved by the FDA and substitutable. It is the source of truth. It is relied upon by P&T committees for their generic medications to be considered for inclusion on the formulary."). These are not things that lay jurors would know.

C. Dr. Panagos's Warranty Opinions Are Not Impermissible Legal Conclusions

As just explained, Dr. Panagos uses the term "warranty" to mean "representation," not as a technical legal term. It is not an "impermissible legal conclusion" to say that Defendants represented to the FDA that the VCDs at issue here were the same as the brand name drug; that the FDA relied on their representations; or that the representations were factually incorrect. Rather, it is a description of how the approval process for the drugs at issue in this case played out, and it should be helpful to the jury. Defendants' citation to *Patrick v. Moorman* for the proposition that an expert may not opine "about the ultimate legal conclusion or about the law or legal standards" (Mot. at 28 (quotation marks omitted)) is misplaced: the expert in *Patrick* would have testified that the conduct of a defendant police officer in a Section 1983 action alleging excessive force was unreasonable, which went directly to the merits of the plaintiff's claim. *See* 536 F. App'x 255, 258 (3d Cir. 2013) ("Baranowski essentially opined that Deputy Moorman's actions were unreasonable and about what a reasonable officer would have done. In a § 1983 suit, 'reasonableness' is practically interchangeable with 'excessiveness', so Baranowski might as well have opined that Deputy Moorman's use of force was excessive."). Dr. Panagos, by contrast, does not opine on the ultimate merits of Plaintiffs' claims. *See also Hanreck v. Winnebago Indus., Inc*., 2019 WL 1383509, at *18 (M.D. Pa. 2019) (cited by Defendants) ("Plaintiffs seek to preclude Hutchcraft from testifying as to legal conclusions such as warranty

coverage and the ultimate issue of whether the warranty was breached. The court agrees that an expert may not present a legal conclusion or opinion.").

IV. DR. PANAGOS'S OPINIONS ON DRUG FORMULARIES AND TPPS' PAYMENT OF VCDS ARE WELL SUPPORTED AND PROPER EXPERT TESTIMONY

A. Dr. Panagos's Opinions as to Whether the TPPs Would or Should Have Paid for VCDs are Supported

Defendants argue that Dr. Panagos's opinions as to "whether TPPs would have or should have paid for VCDs are unsupported and Ipse Dixit." (Mot. at 29.) As a basis for that argument, they claim that Dr. Panagos (1) supposedly knew "little about the [TPP] class of plaintiffs," (2) purportedly "did not conduct any research to confirm" the actions taken by the TPPs after the recall, and (3) "merely repeat[s] her own conclusions." *Id.* at 29-31. But in making that argument, Defendants overstate the scope of Dr. Panagos's opinion and advance arguments that go to the weight of her testimony, rather than its admissibility.

Defendants exaggerate the scope of Dr. Panagos's opinion, claiming that she was "retained to render opinions on behalf of '[a]ll TPPs in the United States and its territories and possessions that, since at least January 1, 2012 to the present, paid any amount of money for valsartan-containing drug. . . .'" (Mot. at 29.) They then attack this expanded version of her opinion as "unsupported" on the theory that Dr. Panagos did not answer some questions as to what the TPPs may have done *after* the VCDs were already on the formulary and the contamination was disclosed. *See* Mot. 30-31 (*e.g.*, "Dr. Panagos evaded questions asking her to identify any TPP in the country that removed VCDs from its formulary. . . .").

But the language that Defendants quote is lifted from the section of the Panagos report that defines a "TPP"—not from the section that contains Dr. Panagos's actual opinions. Notably, and contrary to Defendants' assertions, Dr. Panagos does not purport to be an expert *on all things*

TPP. Rather, her opinion is focused on the decision TPPs made to place the drug on the formulary *before* the VCD contamination was disclosed. Specifically, she opined that the "TPPs and P&T Committees expressly rely upon the manufacturers' compliance with all applicable standards, obligations, and regulations;" that "TPPs rely on an Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations and as such are suitable for formulary replacement and reimbursable under a prescription drug benefit plan"; and that TPPs therefore "paid for medications they should not have paid for. . . ." (D.E. 2034-3 ¶¶ 46, 55, 57.) For that reason, the actions the TPPs may have taken *after* the drug was already on the formulary, and the contamination was disclosed, have little to do with whether there is support for Dr. Panagos's actual opinion about the TPPs' reliance on manufacturer representations in placing the VCDs on the formulary *before* the contamination was disclosed.[7]

Further, Dr. Panagos's actual opinion is well-supported by her more than 20 years of experience in managed care and the pharmacy consulting industry, including overseeing clinical development and overall PBM operations, and working with TPAs and TPPs. Courts routinely find that an expert's opinion can be "supported" based on their "*extensive and specialized experience*." *See Hendricks v. Ford Motor Co.*, 2012 WL 12045429, at *3 (E.D. Tex. 2012). In *Hendricks*, the court explained that "[the] witness' experience, studies and education, combined with a review of the relevant materials can provide a reliable basis for expert testimony." *Id.* In *United States v. Lawson*, the court found the expert's opinion supported by her resume, which

[7] Defendants' argument assumes—without support—that removing a drug from a formulary is no more complex than putting it on a formulary. But as Dr. Panagos testified, it requires "thoughtful, careful" strategies to remove a drug from a formulary. (Panagos Dep. 160:20-161:4.) In any event, this line of argument from Defendants is a diversion, because the record is clear that after the VCD contamination was disclosed, the TPPs took the VCDs off the formularies. *See e.g.*, deposition testimony of Summacare's corporate representative, Tiffanie Mrakovich, *attached as* **Exhibit A** at 95:18-96:9.

showed she had "ten years of experience auditing financial documents, ke[pt] up with continuing professional education, and ha[d] an appropriate educational background for auditing." 2009 WL 1208014, at *5–6 (E.D. Ky. 2009).And in *Fox v. Makarchuk*, the court found that "experience alone—or experience in conjunction with other knowledge, skill, training or education" could provide sufficient support for the expert's opinion. 2021 WL 4146907, at *4 (D. Wyo. 2021).

At best, the Defendants' challenges go to the weight of Dr. Panagos's opinions, which is not a basis to disqualify her under *Daubert*. *See Fox v. Dannenberg*, 906 F.2d 1253, 1256 (8th Cir.1990) (internal citations omitted) ("Once the trial court has determined that a witness is competent to testify as an expert, challenges to the expert's skill or knowledge go to the weight to be accorded the expert testimony rather than to its admissibility. The question of the expert's credibility and the weight to be accorded the expert testimony are ultimately for the trier of fact to determine."); *Campbell v. Fawber*, 975 F. Supp. 2d 485, 500 (M.D. Pa. 2013) (Challenges to the accuracy of an expert's conclusion go to the weight of the evidence rather than its admissibility and can be explored on cross-examination.).

B. Dr. Panagos's Opinions on the Inclusion of VCDs on a Drug Formulary Are Supported

Defendants argue that Dr. Panagos's opinions regarding the "VCDs' placement on drug formularies" should be excluded on the theory that they rely on "Dr. Panagos' own other opinions" about a "warranty," and thus are "unsupported by any reliable principles." But as explained in Section III above, Dr. Panagos's "warranty" opinions are supported.

Her opinion about the placement of the drugs on the formulary does not turn on the legal term "warranty," which she testified she used in the sense of a "promise." (Panagos Dep. 58:21-15.) She could state her opinion just as well without using the word warranty. As Dr. Panagos explained in her report, TPPs and P&T Committees expressly rely upon manufacturers'

compliance with all applicable standards, obligations, and regulations." (D.E. 2034-3 at ¶ 46.) "TPPS rely on an Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations and as such are suitable for formulary replacement and reimbursable under a prescription drug benefit plan." *Id.* at ¶ 55. As a result, "TPPs paid for medications they should not have paid for . . . ." *Id.* at ¶ 57. Because the underlying opinions Defendants challenge are in fact supported and admissible, so is her opinion "that the VCDs were improperly included on drug formularies." (Mot. at 31.)

C. Dr. Panagos Is Qualified to Offer Opinions on Drug Formularies and Payment for VCDs by TPPs

Defendants claim that Dr. Panagos is not qualified because she has not disclosed "any *specific* scope, depth, or frequency of her involvement with creating and managing formularies." (Mot. at 32 (emphasis original).) But neither Rule 26 nor Rule 702 requires such a specific disclosure. And as a qualitative matter, Dr. Panagos only needs to demonstrate that she has "skill or knowledge greater than the average layman." *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (citing *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir. 1987)). As shown in Section I, Dr. Panagos certainly has done so. Her education includes a B.S. and doctorate in pharmacy, and she is a registered pharmacist. She has over 20 years of experience in providing pharmacy benefit guidance to TPPs and TPAs, the subject she will testify about. *See* D.E. 1749-3. And she has served as the Director of Pharmacy Academic Services at Long Island University College of Pharmacy. *Id.*

Defendants object that Dr. Panagos failed to "establish that she has any relevant experience "provid[ing] consultation or advice concerning inclusion of drugs in a formulary," on the theory that she didn't "identify the name of a single TPP or PBM for whom she has worked" due to "confidentiality agreements." (Mot. at 33.) But declining to name the specific TPPs or

PBMs that she consulted for does not negate her testimony that she has over 20 years of experience in providing pharmacy benefit guidance to TPPs, PBMs, and TPAs. *See* D.E. 1749-3. Nor did it preclude defense counsel from inquiring further as to the nature, scope, and duration of that consulting work.[8]

Defendants rely on cases collected in *Waldorf v. Shuta*, 142 F.3d 601 (3d Cir. 1998) to argue that Dr. Panagos's "ten-month employment where she 'set up the pharmacy benefits with regards to formulary'" is insufficient experience. But those cases are inapposite. In *Diaz v. Johnson Matthey, Inc.*, 893 F.Supp. 358, 373 (D.N.J. 1995), the expert was a doctor who had *never* treated anyone with the allergy at issue and had only read one article about its effects. In *Higginbotham v. Volkswagenwerk Aktiengesellschaft*, 551 F.Supp. 977, 982–83 (M.D. Pa. 1982), an officer was not qualified to offer an expert opinion on the movement of a person inside a vehicle during an accident because the officer only had minimal training in preliminary aspects of accident reconstruction. And in *Globe Indem. Co. v. Highland Tank & Manuf. Co.*, 345 F.Supp. 1290, 1291–92 (E.D. Pa. 1972), there was "no evidence that [the expert] had any experience or expertise regarding the proper formulation of safety criteria to be followed in the design of molasses tanks in this particular industrial setting," which was the area in which he sought to testify.

[8] Plaintiffs' counsel made clear on the record during the deposition that defense counsel was free to ask questions about the companies Dr. Panagos has worked with, so long as the name of the company was not disclosed. (Panagos Dep. 159:9-14.) Defense counsel did not take him up on the offer. The situation here is thus markedly different from the situation in *Wicker v. CONRAIL*, on which Defendants rely. 371 F. Supp. 2d 702, 726 (W.D. 2005). In *Wicker*, there was virtually no evidence on the record as to the expert's qualifications because the plaintiff had failed to file the expert's deposition and three of their four reports. The court was therefore unable to ascertain the expert's qualifications. Here, without naming her clients due to a protective order, Dr. Panagos testified extensively as to her work consulting with TPPs, PBMs, and TPAs, and that testimony is in the record, as are her resume and expert report. (D.E. 2034-3; 2034-4.)

This case could not be more different. Not only did Dr. Panagos spend ten months setting up a pharmacy's formulary, she also received a bachelor's degree and a doctorate in pharmacy and has spent more than 20 years dedicated to managed care and the pharmacy consulting industry, including overseeing clinical development and overall PBM operations, and working with TPAs and TPPs. She has "knowledge greater than the average layman" and is qualified to testify as an expert in this case.

D. Dr. Panagos's Opinions on TPPs' Payment for VCDs Will Help the Factfinder

Defendants ask the Court to exclude "Dr. Panagos' opinions that TPPs paid for medications that they should not have" on the theory that the opinions "would not be helpful to the factfinder" because they are "not sufficiently tied to the facts of this case" and "therefore, do not fit." (Mot. at 33-35.) Defendants claim that Dr. Panagos has no independent knowledge of whether any (1) TPPs asked for a refund, (2) TPPs "removed or blocked the recalled VCDs from their formularies," or (3) "there were certain lots of recalled [VCDs] that did not contain . . . NDMA or NDEA." *Id*. at 34. But even if true (something that Plaintiffs do not concede), none of those criticisms would render Dr. Panagos's testimony "unfit." "In assessing whether an expert's proposed testimony 'fits,' we are asking whether [the] expert testimony proffered is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *United States v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010) (quotation marks and citation omitted). Here, Defendants appear to take issue with what the P&T Committees and TPPs relied on when placing the VCDs on the formulary. Dr. Panagos's opinion directly addresses that issue and would aid the jury in resolving it. It therefore "fits" the case.

Further, none of the Defendants' criticisms are even relevant to what the P&T and TPPs relied on when placing the VCDs on the formulary. *See* Section IV(A) above. And even if they

were relevant, they would go to the weight of Dr. Panagos's opinion, not to whether she is qualified. *See Campbell v. Fawber*, 975 F. Supp. 2d 485, 500 (M.D. Pa. 2013).

Lastly, the Defendants' reliance on *In re Suboxone (Bupreorphine Hydrochloride & Naloxone) Antitrust Litig.*, is misplaced. 2020 U.S. Dist. LEXIS 219949 at *70-71 (E.D. Pa 2020). In that case, the proposed expert's testimony "represent[ed] an attempt to end-run inadmissible hearsay into evidence" by "[p]arroting the survey conclusions without offering further analysis. . . ." That is not the case here, where Dr. Panagos will testify based on her specialized knowledge and experience. She is not being used to introduce inadmissible hearsay.

CONCLUSION

Dr. Panagos's testimony is based on her specialized knowledge and will assist the trier of fact to understand the evidence and determine facts in issue, and Dr. Panagos is qualified as an expert by knowledge, skill, experience, training, and education. The Court should deny Defendants' motion to exclude her testimony.

Dated: June 2, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of June 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

/s/ *Jorge Mestre*